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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER MUMMERT, STEPHANIE KANE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/542,558

**Applicant(s)**

CHEN ET AL.

**Examiner**

Stephanie K. Mummert, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9, 11-12, 14-16, drawn to an isolated nucleic acid, expression vector or host cell, classified in class 536, subclass 23.1.
  - II. Claims 10, 13, 30-31, drawn to a method for producing a polypeptide, classified in class 435, subclass 70.1.
  - III. Claims 17-18, drawn to an isolated polypeptide, classified in class 530, subclass 300.
  - IV. Claim 19, drawn to a purified antibody, classified in class 424, subclass 130.1.
  - V. Claims 20-29, 34-35, drawn to a method a method of detecting BCRM-1 polypeptide, classified in class 435, subclass 7.1.
  - VI. Claims 32-33, drawn to a method for targeting a proliferative disorder comprising detecting nucleic acids, classified in class 435, subclass 6.
  - VII. Claims 36-37, drawn to a method for screening for a therapeutic agent, classified in class 435, subclass 455.
  - VIII. Claims 38-39, drawn to a cell system for screening for therapeutic agents, classified in class 435, subclass 325.
  - IX. Claims 40-41, drawn to a method for making an antibody, classified in class 800, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

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1. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the isolated nucleic acids of Group I can be used in methods of hybridization, cloning or mutagenesis. Because the nucleic acids of Group I can be used in methods that are separate and distinct from the method of making a polypeptide, these inventions are distinct. In order to search the nucleic acid of Group I requires text searching of nucleic acid databases and would not necessarily address the method of making a polypeptide as encoded by the isolated nucleic acid. In order to fully search these inventions would require separate and distinct searches. Therefore, it would pose an undue burden to require a search of both inventions together.
3. Inventions I and III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct from one another. Group I is directed to an isolated nucleic acid while the invention of Group III is directed to an isolated polypeptide, encoded by the nucleic acid of Group I. However, while the nucleic acid of Group I encodes the polypeptide of Group III, these products have different design, mode of operation, function and effect. Furthermore, the inventions as claimed do not

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encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

4. Inventions I and IV are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants.

See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct from one another. Group I is directed to an isolated nucleic acid while the invention of Group IV is directed to an isolated antibody, capable of binding to the polypeptide encoded by the nucleic acid of Group I. However, while the nucleic acid of Group I encodes the polypeptide bound by the antibody of Group IV, these products have different design, mode of operation, function and effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. Inventions I and V-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs, modes of operation, effects and are not capable of use together. The invention of Group I is directed to an isolated nucleic acid. The inventions of Groups V-VII and IX, are drawn to multiple methods and Group VIII is drawn to a cell system. Each of these methods do not require or allow the use of the nucleic acids of Group I. The cell system of Group VIII does not require the nucleic acid of Group I, nor are these two inventions disclosed as usable together. Therefore, because these inventions are not usable together or have different modes of operation,

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the inventions are unrelated and require distinct searches that are not coextensive in scope.

Therefore, it would pose an undue burden to require searching of these inventions together.

6. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the isolated polypeptide of Group III could be useful in methods of chromatography or enzymatic assays. Therefore, because the polypeptide of Group III can be used in methods that are separate from methods of making a polypeptide, it would pose an undue burden to require a search of both inventions together. Furthermore, in order to search the polypeptide of Group III would require a text search of polypeptide databases, a search that would not necessarily address the method of making the polypeptide. Therefore, because separate and distinct searches are required for each invention, it would pose an undue burden to require a search of both inventions together.

7. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs, modes of operation, effects and are not capable of use together. The invention of Group II is directed to a method of producing a polypeptide, while the invention of Group VI is directed to a purified antibody. These inventions are not disclosed as capable of use together and they have different modes of operation and different designs.

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8. Inventions II and V are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants.

See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct from one another. The invention of Group II is drawn to a method of producing polypeptides, while the invention of Group V is drawn to a method of detecting polypeptides. These inventions are not disclosed as being capable of use together and each have different modes of operation, function and effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

9. Inventions II and VI-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs, modes of operation, effects and are not capable of use together. The invention of group II is drawn to a method of producing a polypeptide, while the inventions of Groups VI-IX are drawn to unrelated methods and to a cell system. Each of these methods do not relate to the method of making a polypeptide of Group II. The cell system of Group VIII does not relate to the method of making a polypeptide, nor are these inventions disclosed as usable together. Therefore, because these inventions are not usable together or have different modes of operation, the inventions are unrelated and require distinct searches that are not coextensive in scope. Therefore, it would pose an undue burden to require searching of these inventions together.

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10. Inventions III and IV are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants.

See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct from one another. The invention of Group III is directed to an isolated polypeptide, while the invention of Group IV is directed to an isolated antibody capable of binding to the polypeptide of Group III. However, while the antibody is directed against the polypeptide of Group IV, these inventions have materially different designs, modes of operation, functions and effects. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

11. Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the isolated polypeptide of Group III could be useful in methods of chromatography or enzymatic assays. Therefore, because the polypeptide of Group III can be used in methods that are separate from methods of detecting the polypeptide, it would pose an undue burden to require a search of both inventions together. Furthermore, in order to search the polypeptide of Group III would require a text search of polypeptide databases, a search that would not necessarily address the method of detecting the polypeptide. Therefore, because



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separate and distinct searches are required for each invention, it would pose an undue burden to require a search of both inventions together.

12. Inventions III and VI-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs, modes of operation, effects and are not capable of use together. The invention of Group III is directed to an isolated polypeptide, while Groups VI-IX are directed to unrelated methods and a cell system. Each of these methods do not relate to the isolated polypeptide of Group III. The cell system of Group VIII does not relate to polypeptide of Group VI, nor are these inventions disclosed as usable together. Therefore, because these inventions are not usable together or have different modes of operation, the inventions are unrelated and require distinct searches that are not coextensive in scope. Therefore, it would pose an undue burden to require searching of these inventions together.

13. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody of Group IV can be useful in methods of affinity isolation, or in ELISA assay. Therefore, because the antibody of Group IV can be used in methods that are separate from methods of detecting a polypeptide, it would pose an undue burden to require a search of both inventions together. Furthermore, in order to search the polypeptide of Group III would require a text search of prior art databases, a search that would

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not necessarily address the method of detecting the polypeptide. Therefore, because separate and distinct searches are required for each invention, it would pose an undue burden to require a search of both inventions together.

14. Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody of Group IV can be useful in methods of affinity isolation, or in ELISA assay. Therefore, because the antibody of Group IV can be used in methods that are separate from method of modulating expression of Group VI, it would pose an undue burden to require a search of both inventions together. Furthermore, in order to search the polypeptide of Group III would require a text search of prior art databases, a search that would not necessarily address the method of modulating expression. Therefore, because separate and distinct searches are required for each invention, it would pose an undue burden to require a search of both inventions together.

15. Inventions IV and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody of Group IV can be useful in methods of affinity isolation, or in ELISA assay. Therefore, because the antibody of Group IV can be used in methods that are separate from method of screening of Group VII, it would pose an undue

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burden to require a search of both inventions together. Furthermore, in order to search the polypeptide of Group III would require a text search of prior art databases, a search that would not necessarily address the method of screening. Therefore, because separate and distinct searches are required for each invention, it would pose an undue burden to require a search of both inventions together.

16. Inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs, modes of operation, effects and are not capable of use together. The invention of Group IV is directed to an isolated antibody, while Group IX is directed to a cell system. The cell system of Group VIII does not relate to the antibody of Group IV, nor are these inventions disclosed as usable together. Therefore, because these inventions are not usable together or have different modes of operation, the inventions are unrelated and require distinct searches that are not coextensive in scope. Therefore, it would pose an undue burden to require searching of these inventions together.

17. Inventions IV and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody of Group IV can be useful in methods of affinity isolation, or in ELISA assay. Therefore, because the antibody of Group IV can be used in methods that are separate from method of making of Group IX, it would pose an undue burden to require a search of both

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inventions together. Furthermore, in order to search the antibody of Group IV would require a text search of prior art databases, a search that would not necessarily address the method of screening. Therefore, because separate and distinct searches are required for each invention, it would pose an undue burden to require a search of both inventions together.

18. Inventions V and VI-VII, IX are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct from one another. The invention of Group V is directed to a method of detecting polypeptides, while the invention of Group VI-VII and IX are directed to an unrelated methods. The method of detecting polypeptides are not related in any way to the methods of Groups VI-VII or IX. These inventions have materially different designs, modes of operation, functions and effects.

Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

19. Inventions V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the different inventions have different designs, modes of operation, effects and are not capable of use together. The invention of Group V is directed to a method of detecting polypeptides, while Group VIII is directed to a cell system. The cell system of Group VIII does not relate to the method of detecting a polypeptide, nor are these inventions disclosed as usable together.

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Therefore, because these inventions are not usable together or have different modes of operation, the inventions are unrelated and require distinct searches that are not coextensive in scope.

Therefore, it would pose an undue burden to require searching of these inventions together.

20. Inventions VI and VII, IX are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct from one another. The invention of Group VI is directed to a method of modulating expression, while the invention of Group VII and IX are directed to an unrelated methods. The method of modulating expression is not related in any way to the methods of Groups VII or IX. These inventions have materially different designs, modes of operation, functions and effects. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

21. Inventions VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the cell system of Group VIII can be useful in methods of in situ hybridization or in methods of nucleic acid isolation. Therefore, because the cell system of Group VII can be used in methods that are separate from method of screening of Group VIII, it would pose an undue burden to require a search of both inventions together. Furthermore, in

order to search the cell system of Group VII would require a text search of prior art databases, a search that would not necessarily address the method of screening. Therefore, because separate and distinct searches are required for each invention, it would pose an undue burden to require a search of both inventions together.

22. Inventions VII and IX are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct from one another. The invention of Group VII is directed to a method of screening, while the invention of Group IX is directed to an unrelated method. The method of modulating expression is not related in any way to the method of Groups IX. These inventions have materially different designs, modes of operation, functions and effects. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

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examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

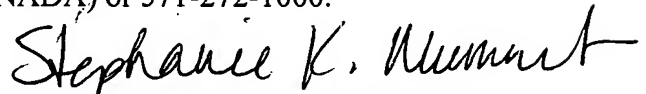
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie K. Mummert, Ph.D. whose telephone number is 571-272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

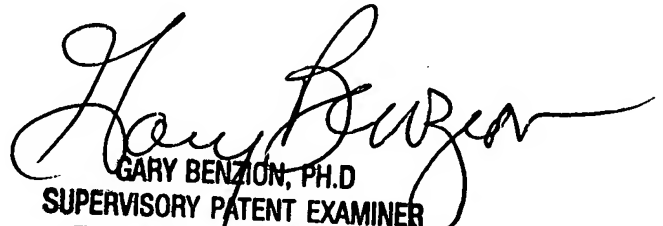


Stephanie K Mummert, Ph.D.

Examiner

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SKM



GARY BENZON, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600